

Notice of Allowability

Application No.

10/820,380

Applicant(s)

BLACK ET AL.

Examiner

Joanne Hama, Ph.D.

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 12/5/07.
2. ☒ The allowed claim(s) is/are 51 and 52.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date _____
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____

Applicant filed an After Final amendment on December 5, 2007. The After Final amendment has been entered.

Claims 51 and 52 have been amended.

Claims 51 and 52 are under consideration.

Withdrawn Rejections

35 U.S.C. § 112, 1st parag., Enablement

Applicant's arguments, see pages 3-5 of Applicant's response, filed December 5, 2007, with respect to the rejection of claims 50 and 51 have been fully considered and are persuasive. Applicant has amended the claims to indicate that the marrow stromal cells are rat or human and that the growth factor used to induce differentiation of the marrow stromal cells was basic fibroblast growth factor. The rejection of claims 50 and 51 has been withdrawn.

35 U.S.C. § 112, 2nd parag.

Applicant's arguments, see page 5 of Applicant's response, filed December 5, 2007, with respect to the rejection of claim 51 have been fully considered and are persuasive. Applicant has amended the claim to indicate that basic fibroblast growth factor induces differentiation of an isolated marrow stroma cell into an insulin secreting cell. The rejection of claim 51 has been withdrawn.

35 U.S.C. § 102

Applicant's arguments, see page 5-6 of Applicant's response, filed December 5, 2007, with respect to the rejection of claims 51 and 52 have been fully considered and are persuasive.

Applicant indicates that Sanchez-Ramos et al. do not teach basic fibroblast growth factor. The rejection of claims 51 and 52 has been withdrawn.

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Ms. Jane Licata on December 18, 2007.

The application has been amended as follows:

1. Claim 51, line 4, the phrase, "that is positive for cell surface markers CD44, CD71, and CD90 and negative for cell surface markers CD11b and CD45" is inserted between "cell" and "with".
2. Claim 52, line 3, the phrase, "that is positive for cell surface markers CD44, CD71, and CD90 and negative for cell surface markers CD11b and CD45" is inserted between "cell" and ",".

The following is an examiner's statement of reasons for allowance: the art closest to the Application is US Patent 6,528,245, Sanchez-Ramos et al., who teach human bone marrow aspirates treated with beta-mercaptoethanol (an antioxidant) and then with EFG or PDGF. Sanchez-Ramos et al. do not teach treatment with bFGF. It is noted that while art generally

teaches media that contains beta-mercaptoethanol and bFGF, the art does not teach the sequential treatment of marrow stromal stem cells with these factors.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joanne Hama, Ph.D. whose telephone number is (571) 272-2911. The examiner can normally be reached on Monday-Friday 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Anne Marie S. Wehbé/
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